

REMARKS

In the Office Action dated July 27, 2006, claims 6-11 were examined with the result that claims 6-11 were all rejected. In response, applicant has rewritten claim 6 and cancelled claim 11. In view of the above amendments and following remarks, reconsideration of this application is requested.

Before turning to the rejections of record, applicant would like to briefly summarize the amendment made to claim 6. Claim 6 has been amended to be limited to increasing the life expectancy of a post menopausal woman by administering an effective amount of the compound 2MD to a post menopausal woman. Thus, the broad language relating to "female human being lacking estrogen" has been restricted to post menopausal women. The amendment to claim 6 also necessitates the cancellation of claim 11.

In the Office Action, claims 6-11 were provisionally rejected under the judicially created doctrine of obviousness double patenting as being unpatentable over claims 30-34 of co-pending Application No. 10/673,629. The Examiner states that although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are drawn to a method of inhibiting tumorogenesis in the treatment of breast cancer while claims 30-34 of the '629 co-pending application are drawn to a method of treating breast cancer by using the same vitamin D compound, i.e. 2MD.

This double patenting rejection by the Examiner, however, is confusing because in applicant's previous Amendment dated May 10, 2006, applicant cancelled all the claims directed toward a method of inhibiting tumorogenesis in the treatment of breast cancer. These claims were refiled in a continuation application on June 25, 2006 which received Application No. 11/472,125. Thus, there are no claims pending in the present application calling for inhibiting tumorogenesis. Although the '629 patent application is directed toward the treatment of cancers such as leukemia, colon cancer, breast cancer and prostate cancer, it is not seen by applicant how this renders a claim such as claim 6 to a method of increasing the life expectancy of a post menopausal woman obvious for double

patenting purposes. Increasing the life expectancy of post menopausal women and treating leukemia, colon cancer, breast cancer and prostate cancer are significantly different pharmaceutical uses for the compound 2MD. It is thus believed that the Examiner should withdraw the obvious type double patenting rejection of claim 6 based upon the '629 patent application.

In the Office Action, claims 6-11 were rejected under 35 USC §103(a) as being unpatentable over U.S. 5,843,928. The Examiner indicates that the reference teaches a method of treating cancers, and the present claims are directed towards a method of increasing the life expectancy of a female human being lacking estrogen, and therefore the present claims are encompassed by a method of treating cancer. It appears that what the Examiner is saying is that by treating cancer with the compound 2MD, one is also increasing the life expectancy of that person. However, the statements made by the Examiner in the Office Action are confusing since the Examiner states that the present application is directed toward treating tumors whereas the '928 patent is directed toward treating cancer. However, as noted above, the claims directed toward treating tumorogenesis have been cancelled from the present patent application. The Examiner seems to be saying that since the data show increased life expectancy due to the inhibition of tumorogenesis, a method of increasing life expectancy as claimed would be obvious in view of the disclosure teaching treatment of cancer with 2MD in the '928 prior art patent.

The Examiner also states that it is unclear whether the data obtained from female rats used in the experiment relates to a lack of estrogen. Again, although it is clear that the female rats utilized in the experiments reported in the specification were ovariectomized, it appears that the Examiner is taking a broad interpretation of the phrase "lacking estrogen". However, as previously noted herein, claim 6 is now specifically limited to increasing the life expectancy of post menopausal women. Applicant believes the data clearly support the increased life expectancy of treated post menopausal women.

It has long been recognized that a rat model is indicative of what might happen in humans, and has long been established as an acceptable model for correlating biological

data to humans. Thus, data in rats has been for many years correlated to humans, and applicant believes that rat data evidencing increasing life expectancy in ovariectomized rats correlates to increasing life expectancy in post menopausal women. If the Examiner desires, applicant can cite numerous published articles that support its position. However, the fact that rat models correlate to human models has long been accepted by those skilled in the art.

Ovariectomized female rats were utilized in the experiments because ovariectomized female rats will generally develop mammary tumors and the experiments were initially designed to determine whether 2MD would be effective to prevent tumorigenesis in the mammary of these older ovariectomized female rats. Surprisingly, however, it was also noticed that the survival rate of these female rats was significantly increased if they were administered 2MD. The experiment set forth on pages 6-7 of the specification was carried on for 7-1/2 months with one-half of the animals receiving a vehicle and the other half of the animals receiving 2MD. All other conditions were the same, i.e. all animals were substantially identical, they received substantially the same diet, and they were housed in a substantially identical environment. During the course of the 7-1/2 month experiment, all animals that received 2MD survived and were in good health. In contrast, at least three of the control animals failed to survive due to the development of mammary tumors. A fourth died of unknown causes. These data clearly show that all of the treated animals survived, thus increasing their life expectancy, whereas a significant number of the untreated animals failed to survive due to the development of cancerous breast tumors. It is to be particularly noted that the data in Table 1 is in fact statistically significant. Applicant believes the data illustrate increased life expectancy, and thus the data support claim 6 as herein amended. As noted in the experiment, 16.7% of the rats (4 of 24) died in the untreated or control group whereas 0% of the rats died in the group treated with 2MD.

In addition, since the rats were all retired female breeder rats 12 months of age or older, and were all ovariectomized, applicant believes the data further illustrate the ability

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of 2MD to increase the life expectancy of post menopausal women. Clearly, all of the rats were females and all lacked estrogen due to being ovariectomized. All of the rats treated with 2MD survived, and thus had increased life expectancy over those in the untreated group, a significant number of which died. Thus, applicant believes these data support claim 6, especially since the use of ovariectomized female rats is an accepted model for post menopausal women.

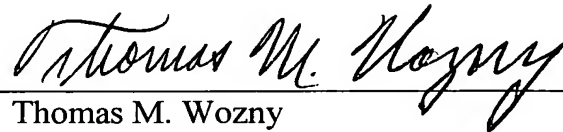
Accordingly, applicant requests the Examiner to withdraw the §103(a) rejection of the claims.

An effort has been made to place this application in condition for allowance and such as is earnestly requested.

Respectfully submitted,

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